

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

CATHY BALURA, *et al.*,

Plaintiffs,

-against-

3:19-CV-1372 (LEK/ML)

ETHICON, INC., *et al.*,

Defendants.

MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

Plaintiffs Cathy and Peter Balura are among the thousands of plaintiffs who have sued defendants Ethicon, Inc. and Johnson & Johnson (together, “Defendants”) for injuries caused by Defendants’ allegedly defective pelvic mesh products. There are two issues currently before the Court. First, unopposed by Plaintiffs, Defendants have moved for partial summary judgment on thirteen causes of action listed in the complaint. See Dkt. Nos. 34 (“SJ Motion”); 35 (“SJ Memorandum”); 39 (“Plaintiffs’ SJ Response”); see also Dkt. No. 1 (“Short Form Complaint”). And second, Defendants move to exclude the opinions and testimony of Plaintiff’s case-specific expert, Michael T. Margolis, M.D. (“Dr. Margolis”). Dkt. Nos. 37 (“Motion to Exclude”); 38 (“Motion to Exclude Memorandum”); see also Dkt. Nos. 40 (“Opposition”); 41 (“Reply”). For the following reasons, the Court dismisses the thirteen causes of action and grants in part and denies in part the Motion to Exclude.

II. BACKGROUND

This case is part of the massive products liability multi-district litigation (“MDL”) against Defendants ongoing around the country. See In re Ethicon, Inc., Pelvic Repair System Products Liability Litigation, No. 12-MD-2327. The product at issue is “transvaginal surgical mesh” used

primarily “to treat pelvic organ prolapse and stress urinary incontinence.” In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., No. 13-CV-12719, 2017 WL 6345880, at *1 (S.D.W. Va. Dec. 11, 2017).

A. Facts

Cathy Balura lives with her husband, Peter, in Stamford, New York.¹ Dkt. No. 26 (“Plaintiff Profile Form”). In 2009, Mrs. Balura was diagnosed with stress urinary incontinence (“SUI”). Opp’n at 4.² To treat the SUI, on May 7, 2009, Mrs. Balura had surgery in which doctors implanted Defendants’ Gynecare transvaginal tape (“TVT”) in her pelvis.³ Id. This surgery took place in Oneonta, New York. Dkt. No. 37-1.

Nine to twelve months after the surgery, Mrs. Balura’s SUI returned. Dkt. No. 37-2 (“Plaintiff Fact Sheet”) at 7. Additionally, when she resumed having a sexual relationship with Mr. Balura, she experienced “sharp pain” and Mr. Balura felt “[s]harp edges” of the mesh inside of Mrs. Balura. Dkt. Nos. 37-3 (“Cathy Balura Deposition Excerpts”) at 94–95; 37-4 (“Peter Balura Deposition Excerpts”) at 20, 46.

On April 19, 2013, Mrs. Balura saw Dr. Robert Lobel, complaining of vaginal bleeding, dyspareunia (pain during intercourse), and “feeling something in the vagina.” Dkt. No. 40-1

¹ Because Cathy and Peter Balura share the same last name, the Court refers to them as Mrs. and Mr. Balura, respectively.

² When citing to Plaintiffs’ Opposition, the Court refers to the page numbers generated by CM/ECF, the Court’s electronic filing system.

³ A TVT is a medical device in the form of a mesh tape, or sling, that is placed under the urethra to provide support to the urethra. See Edwards v. Ethicon, Inc., No. 12-CV-9972, 2014 WL 3361923, at *1 (S.D.W. Va. July 8, 2014).

(“Opposition Exhibits”) at 10–11.⁴ She described how the TVT had helped with her SUI for almost a year, but that now she was again having problems with incontinence. Id. She also described having difficulty emptying her bladder and that she had to change positions to do so. Id. Dr. Lobel examined Mrs. Balura and found that she suffered from eroded vaginal mesh, dyspareunia, recurrent urinary incontinence (stress and urge) and a symptomatic fibroid uterus. Id. However, relevant to the Motion to Exclude addressed below, Dr. Lobel testified in his deposition that he had not found “any excessive contraction or scarification around the mesh” during his vaginal exam of Mrs. Balura. Dkt. No. 37-7 (“Lobel Deposition Excerpts”) at 29. Dr. Lobel also testified that he had not found chronic inflammation, id. at 35, nor seen “any indication in the records of any evidence that Ms. Balura had bladder outlet obstruction,” id. at 56.

To address these symptoms, Mrs. Balura had a “revision” surgery on May 21, 2013 at Albany Memorial Hospital in Albany, New York. Dkt. No. 37-5. During the surgery, Dr. Lobel removed the eroded part of Defendants’ TVT and performed a vaginal hysterectomy. Id. After the revision surgery, Mrs. Balura continued to experience incontinence and pain during intercourse. Opp’n Exs. at 34.

B. Relevant Procedural History

In February 2012, all the cases related to the In re Ethicon, Inc., Pelvic Repair System Products Liability Litigation, MDL No. 2327 were transferred to the District Court for the Southern District of West Virginia (the “MDL court”). See In re: Am. Med. Sys., Inc., Pelvic Repair Sys. Prod. Liab. Litig., 844 F. Supp. 2d 1359, 1361 (U.S. Jud. Pan. Mult. Lit. 2012). The

⁴ Because Plaintiffs have filed all their Exhibits as a single document, when citing to the Exhibits, the Court refers to the page numbers generated by CM/ECF.

Honorable Joseph R. Goodwin, U.S. District Judge, continues to preside over the In re Ethicon MDL in that district.

On November 16, 2012, Plaintiffs filed this lawsuit in the Southern District of West Virginia. Short Form Compl. The case proceeded through discovery, and, on May 22, 2017, Plaintiffs named their expert witnesses, including four general experts and Dr. Margolis as their case-specific expert. Opp'n Exs. at 58–58.

On August 8, 2017, Defendants moved for partial summary judgment. SJ Mot. However, on August 22, 2017, Plaintiffs responded that they “did not intend to pursue any of the claims on which [Defendants] sought partial summary judgment,” and agreeing to dismiss those causes of action. Pls.' SJ Resp. at 1.

During that same period, on August 15, 2017, Defendants filed their Motion to exclude Dr. Margolis’ testimony. Mot. to Exclude. Plaintiffs filed their Opposition on August 29, 2017, and Defendants filed their Reply on September 5, 2017. See Docket.

On October 30, 2019, Judge Goodwin ordered this case transferred to this Court, “the venue from which [it] arise[s],” for resolution. Dkt. No. 60 (“Transfer Order”).

C. Dr. Margolis’ Expert Report

Before turning to the applicable law, the Court summarizes Dr. Margolis’ expert report. In preparing his report, Dr. Margolis reviewed the medical records, depositions, and deposition exhibits in this case, and he relied on his “training, education, and experience.” Dkt. No. 37-8 (“Margolis Report”) at 1. Apparently, Dr. Margolis did not examine Mrs. Balura herself. See generally Id.

Dr. Margolis described Mrs. Balura’s medical history, including her initial surgery to implant the TVT and subsequent complications. Id. at 1–2. Then he stated that, “[t]o [sic]

reasonable degree of medical certainty, Ms. Balura's pelvic injuries were caused by the defective TTVT device.” Id. at 2.

To reach his conclusion, Dr. Margolis described Mrs. Balura's symptoms, “including delayed erosion, dyspareunia, husband dyspareunia, recurrence of her incontinence from failure of the sling and the need for its removal, partial bladder outlet obstruction and chronic inflammation from the sling.” Id. at 3. He then used a “differential diagnosis” to “rule out any other potential causes of Ms. Balura's pelvic injuries” besides Defendants' TTVT sling.⁵ Id. at 2.

Dr. Margolis next opined that Mrs. Balura “is at risk for future delayed erosions.” Id. at 3. He also stated that “[s]he will continue to have dyspareunia from the sling and its effects on the body” and “[s]he will continue to have worsening urinary incontinence which will eventually require another operative procedure to correct.” Id. Finally, Dr. Margolis opined that “[f]uture surgeries will be far more complicated in her because of the dense scar tissue caused by the sling, and more likely than not will increase scarring, related pain and tissue damage.” Id.

III. DISCUSSION

The Court addresses, in turn: (A) the choice of law issues in this case; (B) Plaintiffs' request for dismissal; and (C) Defendants' motion to exclude.

A. Choice of Law

As a preliminary matter, the Court must determine which jurisdiction's law governs this case. It does so bearing in mind that orders previously issued by an MDL court should generally remain binding once an individual case is sent back to its home venue. See Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d 420, 428 (E.D.N.Y. 2011) (“[In an MDL,] the law of the case

⁵ “Differential Diagnosis is “a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes.” Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (internal quotation marks omitted).

doctrine ‘posits that when a court decides a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.’”) (quoting Arizona v. California, 460 U.S. 605, 618 (1983)).

“This case is based on diversity jurisdiction. Federal law thus controls procedural issues and state law controls substantive issues.” Sanchez v. Bos. Sci. Corp., No. 12-CV-5762, 2014 WL 202787, at *3 (S.D.W. Va. Jan. 17, 2014); see also Jazini v. Nissan Motor Co., 148 F.3d 181, 183 (2d Cir. 1998) (“In diversity cases the federal courts generally apply state law in deciding substantive questions and federal law in deciding procedural ones.”). For procedural issues governed by federal law, the Court applies this circuit’s “interpretations of federal law, not the constructions of federal law of the transferor circuit.” Charles Schwab Corp. v. Bank of Am. Corp., 883 F.3d 68, 82 (2d Cir. 2018); see also Adams v. Bos. Sci. Corp., 177 F. Supp. 3d 959, 962 (S.D.W. Va. 2016) (“When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located.”). And the MDL court previously ruled that, when determining which state’s law should govern substantive issues, courts should look to the choice of law provisions in “the place where the plaintiff was implanted with the product.” In re Ethicon, Inc., No. 12-MD-2327, 2014 WL 346717, at *7 (S.D.W. Va. Jan. 30, 2014).

Because Mrs. Balura’s implant surgery took place in New York State, see Dkt. No. 37-1, New York choice of law rules apply. Defendants argue—and Plaintiffs do not dispute—that under New York choice of law rules, New York tort law applies to Plaintiffs’ claims. See SJ Mem. at 2 (“[T]he laws of New York apply to the claims addressed in this motion because . . . Ms. Balura was implanted with the TVT-O in New York.”) (citing Padula v. Lilarn Props. Corp., 644 N.E.2d 1001, 1002 (N.Y. 1994)) (other citations omitted). In the absence of any objection from Plaintiffs, and because all the significant contacts lie in the state of New

York, see Padula, 644 N.E.2d at 1002 (describing how New York choice of law rules require a court to decide “what are the significant contacts and in which jurisdiction are they located”), the Court applies New York substantive law to Plaintiffs’ claims.

B. Request for Dismissal

Federal Rule of Civil Procedure 41(a)(1)(ii) provides that “an action may be dismissed by the plaintiff without order of court . . . by filing a stipulation of dismissal signed by all parties who have appeared in the action.” Fed. R. Civ. P. 41. “Absent a stipulation of dismissal by all parties, FRCP 41(a)(2) provides that ‘an action may be dismissed at the plaintiff’s request only by court order, on terms that the court considers proper.’” Byng v. Campbell, No. 07-CV-471, 2009 WL 3165885, at *2 (N.D.N.Y. Sept. 28, 2009) (quoting Fed. R. Civ. P. 41(a)(2)). “[T]he presumption in this circuit is that a court should grant a dismissal pursuant to [FRCP] 41(a)(2) absent a showing that defendants will suffer substantial prejudice as a result.” Anselmo v. Woodruff, No. 19-CV-69, 2019 WL 4081643, at *1 (N.D.N.Y. Aug. 29, 2019). “The Second Circuit has set forth factors that are relevant to a district court’s determination of whether a defendant would be prejudiced by dismissing an action,” including:

- (1) plaintiff’s diligence in bringing the motion; (2) any undue vexatiousness on plaintiff’s part; (3) the extent to which the suit has progressed; (4) the duplicative expense of relitigation; and (5) the adequacy of plaintiff’s explanation for the need to dismiss.

Id. (citing Zagano v. Fordham Univ., 900 F.2d 12, 14 (2d Cir. 1990)).

Here, Defendants moved for summary judgment on the following causes of action listed in the Short Form Complaint: Count I – Negligence – Manufacturing Defect; Count II – Strict Liability – Manufacturing Defect; Count IV – Strict Liability – Defective Product; Count VI – Common Law Fraud; Count VII – Fraudulent Concealment; Count VIII – Constructive Fraud; Count IX – Negligent misrepresentation; Count X – Negligent Infliction of Emotional Distress;

Count XI – Breach of Express Warranty; Count XII – Breach of Implied Warranty; Count XIII – Violation of Consumer Protection Laws; Count XV – Unjust Enrichment; and Count XVIII – Discovery Rule and Tolling. See SJ Mot. Rather than filing an opposition, Plaintiffs' responded that they “agree[d]” to dismiss those claims.⁶ Pls.’ SJ Resp. However, Plaintiffs’ response is not styled as a “stipulation of dismissal” and is not “signed by all parties who have appeared in the action” as required for voluntary dismissal under FRCP 41(a)(1). See Id. Therefore, in an abundance of caution, the Court evaluates Plaintiffs’ requested dismissal under FRCP 41(a)(2).

Given that Defendants moved for summary judgment on the same claims that Plaintiffs now “agree” to dismiss, and that they filed no objections to Plaintiffs’ request for dismissal, see Docket, it appears that Defendants have no objection to the Court dismissing the claims, see Dkt. No. 39-1 (email correspondence between Plaintiffs’ and Defendants’ counsel discussing “stip to dismiss claims”). Additionally, the Zagano factors that apply here weigh in favor of granting dismissal, as there does not appear to be any undue vexatiousness on the part of Plaintiffs, Plaintiffs filed their request well before this case was transferred from the MDL court, and Plaintiffs appear to abandon the claims in their request because the claims are not viable under New York law. See SJ Mem. Therefore, the Court grants Plaintiffs’ request and dismisses the above causes of action. See Anselmo, 2019 WL 4081643, at *2 (granting plaintiff’s request for dismissal under FRCP 41(a)(2) where defendant indicated that he had no objection to the dismissal).

⁶ Plaintiffs noted in their request for dismissal that, while they “agree[d] to dismiss Count VII – Fraudulent Concealment” and “Count XVIII – Discovery Rule and Tolling” “as . . . independent cause[s] of action,” they were “not waiving or abandoning their right to assert that [D]efendants engaged in conduct that constitutes fraudulent concealment that equitably tolls the statute of limitations” or “their right to assert the discovery rule as a doctrine to toll the commencement of the limitations period.” Pls.’ SJ Resp. at 2. Defendants lodged no objections to these stipulations.

The following claims remain live in this case: Count I – Negligence – Failure to Warn and Design Defect; Count III – Strict Liability – Failure to Warn; Count V – Strict Liability – Design Defect; Count XIV – Gross Negligence; Count XVI – Loss of Consortium; Count XVII – Punitive Damages. Pls.’ SJ Resp. at 2.

C. Motion to Exclude Expert Testimony

Defendants move to exclude Dr. Margolis’ testimony on three grounds: (a) “Dr. Margolis’ inadequate differential diagnosis is replete with factual errors,” which “prohibit him from forming a proper foundation for his opinions”; (b) Dr. Margolis’ “opinion that Ms. Balura’s ‘pelvic injuries’ were caused by the ‘defective’ TVT device without specifying any design defect is insufficient under New York law and therefore not helpful to the finder of fact”; and (c) Dr. Margolis’ “opinions about Ms. Balura’s alleged future complications are speculative and unreliable.” Mot. to Exclude Mem. at 1. Defendants do not challenge Dr. Margolis’ qualifications. See generally Id. The Court addresses in turn: (1) the legal standard governing a motion to exclude expert testimony; and (2) each of Defendants’ three grounds for exclusion.

1. Legal Standard

The admissibility of expert testimony is governed by Federal Rule of Evidence (“FRE”) 702 and the framework laid out in Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993) and its progeny. See Lara v. Delta Int’l Mach. Corp., 174 F. Supp. 3d 719, 727 (E.D.N.Y. 2016). FRE 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In applying FRE 702, the district court must ensure that “an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” Amorgianos v. Nat’l R.R. Passenger Corp., 303 F.3d 256, 265 (2d Cir. 2002) (citing Daubert, 509 U.S. at 597). “Thus, . . . the district court must make several determinations before allowing expert testimony: (1) whether the witness is qualified to be an expert; (2) whether the opinion is based upon reliable data and methodology; and (3) whether the expert’s testimony on a particular issue will assist the trier of fact.” Bee v. Novartis Pharm. Corp., 18 F. Supp. 3d 268, 300 (E.D.N.Y. 2014) (citing Nimely v. City of New York, 414 F.3d 381, 396–97 (2d Cir. 2005)).

Under Daubert, a court must first determine whether the expert is qualified to testify through her or his “knowledge, skill, experience, training, or education.” See Zaremba v. Gen. Motors Corp., 360 F.3d 355, 360 (2d Cir. 2004) (stating that, where the witness lacked qualifications, an analysis of the remaining Daubert factors “seems almost superfluous”); see also Fed. R. Evid. 702. A court should look at the totality of the expert’s qualifications in making this assessment. See, e.g., Rosco, Inc. v. Mirror Lite Co., 506 F. Supp. 2d 137, 144–45 (E.D.N.Y. 2007). Finally, the court must ensure that the expert will testify on subjects that are within her or his area of expertise. See Stagl v. Delta Air Lines, Inc., 117 F.3d 76, 81 (2d Cir. 1997).

As for reliability, “the district court should consider the indicia of reliability identified in [FRE] 702, namely, (1) that the testimony is grounded on sufficient facts or data; (2) that the testimony is the product of reliable principles and methods; and (3) that the witness has applied the principles and methods reliably to the facts of the case.” United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007) (internal citation and quotation marks omitted). Additionally, Daubert “identified a number of factors bearing on reliability that district courts may consider,” such as:

(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) a technique’s known or potential rate of error, and the existence and maintenance of standards controlling the technique’s operation; and (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community.

Amorgianos, 303 F.3d at 266 (internal citations and quotation marks omitted) (citing Daubert, 509 U.S. at 593–94). These criteria are illustrative, not a “definitive” checklist. See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 151 (1999). Moreover, “in addition to these criteria for determining whether the methodology is reliable, [FRE] 702 also requires that there be a sufficiently reliable connection between the methodology and the expert’s conclusions for such conclusions to be admissible.” Bee, 18 F. Supp. 3d at 301 (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)).

With respect to whether the expert’s testimony will assist the trier of fact, “[t]his condition goes primarily to relevance.” Daubert, 509 U.S. at 591; see also In re: Ethicon, Inc., No. 12-MD-2327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016) (“[S]imply, relevance turns on whether the expert testimony relates to any issues in the case.”). “The Daubert court described this consideration as one of ‘fit,’ requiring a ‘valid scientific connection’ between the subject matter of the expert’s testimony and the factual issues to be determined by the jury.” In re Zyprexa Prod. Liab. Litig., 489 F. Supp. 2d 230, 283 (E.D.N.Y. 2007) (quoting Daubert, 509 U.S. at 591–92). Additionally, testimony that “usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it,” United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir. 1991), does not “aid the jury in making a decision”; rather, it “undertakes to tell the jury what result to reach,” and thus “attempts to substitute the expert’s judgment for the jury’s,” United States v. Duncan, 42 F.3d 97, 101 (2d Cir. 1994) (emphasis omitted).

If the proffered expert testimony satisfies the above three-part test under Daubert and FRE 702, a court must finally consider whether the testimony’s “probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . .” Fed. R. Evid. 403; accord Nimely, 414 F.3d at 397. The proponent of the expert testimony bears the burden of establishing the admissibility of such testimony by a preponderance of the evidence. See Daubert, 509 U.S. at 592 n.10.

“Ultimately, whether expert testimony is admissible at trial is a question of law which rests squarely within the broad discretion of the trial judge.” See Lara, 174 F. Supp. 3d at 727; see also Williams, 506 F.3d at 160 (“[T]he district court is the ultimate ‘gatekeeper.’”). Thus, “[t]he standard governing the admissibility of expert testimony is liberal and flexible.” Hilaire v. DeWalt Indus. Tool Co., 54 F. Supp. 3d 223, 234 (E.D.N.Y. 2014). However, despite this liberality and flexibility, the court’s over-arching “gatekeeping” role requires that it “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the field.” Kumho, 526 U.S. at 152. Overall though, “the rejection of expert testimony is the exception rather than the rule.” Argonaut Ins. Co. v. Samsung Heavy Indus. Co., 929 F. Supp. 2d 159, 164 (N.D.N.Y. 2013).

2. Defendants’ three grounds for exclusion

a. The Reliability of Dr. Margolis’ Differential Diagnosis

Defendants’ first object that Dr. Margolis’ “differential diagnosis [is so] replete with factual errors” that it is “unreliable.” Reply at 1. The Court disagrees.

The crux of Defendants’ argument is that “Dr. Margolis ascribed a set of conditions purportedly caused by the TTV to Ms. Balura that are not documented in her medical records

and have not been articulated by Ms. Balura.” Id. at 2. Specifically, they point out that Dr. Margolis’ report stated: “This patient suffered complications from the sling including . . . partial bladder outlet obstruction and chronic inflammation . . . [and] [f]uture surgeries will be far more complicated in her because of the dense scar tissue caused by the sling . . .” Id. (citing Margolis Report at 4. But, Defendants continue, “there is no medical documentation” that Mrs. Balura suffered from any of these three conditions, and in fact, Dr. Lobel testified at his deposition that he had seen no evidence of a bladder outlet obstruction, excessive scarification, or inflammation when he examined Mrs. Balura. Id. (citing Lobel Depo. Excerpts at 29, 35–35, 56). Additionally, Defendants point out that Mrs. Balura testified that she did not suffer from “generalized pelvic pain” or vaginal pain outside of intercourse. Id. at 3 (citing Cathy Balura Depo. Excerpts at 92–94. Finally, Defendants remind the Court that Dr. Margolis did not personally examine Mrs. Balura, and thus his attributing these symptoms to her is “based on nothing more than speculation.” Id. at 2.

It appears to the Court that Defendants’ description of the record before the Court is correct, and Plaintiffs do not challenge that description. Opp’n at 6. Dr. Margolis does appear to attribute to Mrs. Balura the above symptoms that, according to the record, she did not have. However, what Defendants fail to point out is that Dr. Margolis also ascribed to Mrs. Balura many symptoms that, according to her medical records and deposition testimony, she did have. Specifically, Dr. Margolis stated accurately that Mrs. Balura suffered from “delayed erosion, dyspareunia, husband dyspareunia, recurrence of her incontinence from failure of the sling and the need for its removal.” Margolis Report at 4; see also Cathy Balura Depo. Excerpts at 94–95; Peter Balura Deposition Excerpts at 20, 46; Opp’n Exs. at 10–11. Furthermore, through a differential diagnosis, a method that has been blessed by the MDL court and courts in this

circuit,⁷ Dr. Margolis attributed these symptoms to Defendants' mesh sling. *Id.* at 3–4. Notably, Defendants do not challenge the reliability of Dr. Margolis' methodology, the differential diagnosis; instead they challenge his inputs, the facts that he fed into his differential diagnosis. Reply at 3 (explaining that Defendants challenge "Dr. Margolis"[] improper use of an otherwise acceptable methodology" because Dr. Margolis "based [his differential diagnosis] on inaccurate facts").

However, it is not clear to the Court that the Dr. Margolis' reference to some inaccurate facts in his opinion contaminates the reliability of his diagnosis as to the accurate facts. After all, not every mistake in an expert's reasoning necessarily renders the expert's opinion inadmissible. Amorgianos, 303 F.3d at 267. Dr. Margolis' factual missteps here are not, in the Court's eyes, "large enough [to suggest] that [Dr. Margolis] lacks good grounds for his . . . conclusion[]" that the symptoms he accurately identified were caused by Mrs. Balura's TVT implant. *Id.* (citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 746 (3d Cir. 1994)); see also Green Mountain Chrysler Plymouth Dodge Jeep v. Crombie, 508 F. Supp. 2d 295, 316–17 (D. Vt. 2007) (ruling that objections to one of several data sources supporting expert's conclusions are insufficient to render testimony inadmissible). This is particularly true where Dr. Margolis' principles and methodology appear sound and remain essentially unchallenged, see Amorgianos, 303 F.3d at 266 ("[T]he district court must focus on the principles and methodology employed by the expert."), and the evidence that is found in the record supports Dr. Margolis' diagnosis, Opp'n at

⁷ See, e.g., Edwards v. Ethicon, Inc., 2014 WL 3361923, at *3 ("A reliable differential diagnosis passes scrutiny under Daubert."); McCulloch v. H.B. Fuller Co., 61 F.3d 1038, 1043–44 (2d Cir. 1995) (rejecting defendant's argument that differential diagnosis does not qualify as "scientific" under Daubert); Davids v. Novartis Pharm. Corp., 857 F. Supp. 2d 267, 278–79 (E.D.N.Y. 2012) (admitting expert's specific causation testimony based on differential diagnosis).

6 (“Dr. Margolis’ opinions on the cause of Mrs. Balura’s experiencing mesh erosion and mesh revision surgery are certainly reliable and admissible as these injuries cannot occur absent pelvic mesh implants.”).

The Court does not think that the good data upon which Dr. Margolis based his report are “simply inadequate to support the conclusions reached,” see Amorgianos, 303 F.3d at 266, and therefore, the Court finds that Defendants’ arguments go to the weight of Dr. Margolis’ testimony, not its admissibility. See Gonyea v. Irick Excavating, LLC, No. 08-CV-242, 2010 WL 11606974, at *3 (D. Vt. Aug. 12, 2010) (“[T]o [the]extent [a] challenging party asserts gaps or inconsistencies in [the] reasoning leading to [a] doctor’s proffered expert opinion, ‘such arguments go to the weight of the evidence, not its admissibility.’”) (quoting Campbell ex. rel. Campbell v. Metro. Prop. and Cas. Ins. Co., 239 F.3d 179, 186 (2d Cir. 2001)). If Defendants wish to minimize the weight of Dr. Margolis’ opinion, they can bring out his inaccurate statements about Mrs. Balura’s condition on cross-examination. See Daubert, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”). Thus, the Court sees no reason to exclude Dr. Margolis’ opinion as unreliable. See Dover v. British Airways, PLC (UK), 254 F. Supp. 3d 455, 459 (E.D.N.Y. 2017) (“[T]he possibility of mistake [by an expert] need only be tolerable, not remote. Within that tolerable range, disputes over competing expert opinions are to be resolved by the trier of fact.”).

b. Dr. Margolis’ Opinion that “Defects” in the Mesh Caused Mrs. Balura’s Injuries

The Court addresses Defendants’ arguments separately with regard to Plaintiffs’ design defect causes of action and their other causes of action.

i. Causes of Action for Design Defect

Defendants next object that Dr. Margolis’ “ultimate opinion that Mrs. Balura’s alleged ‘pelvic injuries’ were caused by the ‘defective’ TVT device without identifying any design defect is . . . unhelpful to the jury.” Reply at 1; see also Reply at 3–5 (citing Margolis Report at 3 (stating, without more, that “Ms. Balura’s pelvic injuries were caused by the defective TVT device”)). With respect to Plaintiffs’ design defect claims, the Court agrees with Defendants that Dr. Margolis’ opinion is inadmissible.

To establish a *prima facie* case of design defect under New York law, “plaintiffs must establish that (1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing her injury.⁸ Argonaut, 929 F. Supp. 2d at 171–72 (citing Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 108 (1983)). “Additionally, to establish a *prima facie* case, the plaintiff is required to show that the defectively designed product caused his injury and that the defect was the proximate cause of the injury.” Voss, 59 N.Y.2d at 109; see also id. at 109–10 (“The tie which proximate cause is to provide in order to impose legal liability must be between the design defect of the product and the injury.”). Causation has two components: general and specific. In re Mirena IUD Prod. Liab. Litig., 202 F. Supp. 3d 304, 310 (S.D.N.Y. 2016), aff’d, 713 F. App’x 11 (2d Cir. 2017). “General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual’s injury.” In re Rezulin Prod., No. 00-CV-2843, 2004

⁸ The same elements apply regardless of whether a plaintiff brings a design defect claim under a negligence or a strict liability theory. See Argonaut, 929 F. Supp. 2d at 177 (“Although plaintiffs assert the design defect claim under theories of strict products liability and negligence, the same *prima facie* case is required under both theories.”) (citing Jarvis v. Ford Motor Co., 283 F.3d 33, 62–63 (2d Cir. 2002)).

WL 2884327, at *2 (S.D.N.Y. Dec. 10, 2004) (“General causation [asks whether] smoking cigarettes can cause lung cancer . . . Specific, or individual, causation [asks whether] a specific plaintiff’s lung cancer was caused by his smoking.”).

Here, Plaintiffs offer Dr. Margolis’ testimony to prove specific causation and the testimony of their other named experts to prove general causation. See Opp’n Mem. at 8 (“Plaintiffs have designated four other experts, including a general causation expert and materials expert, to assist the jury . . .”); id. at 9 (“Dr. Margolis’ opinions fulfill the requirements of admissibility of a specific causation expert . . .”). They argue that “Dr. Margolis is one of five expert witnesses designated . . . to prove the TVT was defective and the cause of [Mrs. Balura’s] injuries.” Id. at 7. However, Dr. Margolis is Plaintiffs’ sole specific causation expert, and so it must be his testimony that “tie[s]” “the design defect of the product” to “the injury,” as is necessary to establish a design defect claim under New York law. Voss, 59 N.Y.2d at 110. The opinions of Plaintiffs’ remaining four experts, though necessary to prove other aspects of their case, do not speak to specific causation and are irrelevant to this particular question.

And on the question of specific causation, Dr. Margolis’ report is deficient. While he concludes that “Ms. Balura’s pelvic injuries were caused by the defective TVT device,” Dr. Margolis fails to describe or explain how a *defect* in the TVT caused Mrs. Balura’s injuries, as opposed to the mere presence of the TVT itself. See Gilks v. Olay Co., 30 F. Supp. 2d 438, 443 (S.D.N.Y. 1998) (“Mere use of the product and subsequent injury . . . are not a sufficient basis from which to infer causation.”). Without such an explanation, the Margolis Report does not address the specific issue—how a mesh *defect* caused Mrs. Balura’s injuries, as opposed to the mere presence of the mesh—for which it has been offered as evidence and must be excluded as

unhelpful. See Colon v. Abbott Labs., 397 F. Supp. 2d 405, 416 (E.D.N.Y. 2005) (“A district court is not required to admit opinion evidence which is ‘connected to existing data only by the ipse dixit of the expert.’”) (quoting Gen. Elec., 522 U.S. at 146; Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 710 (S.D.W. Va. 2014) (“An expert’s testimony must help the jury . . . ‘to determine a fact in issue.’” (quoting Fed. R. Evid. 702)).

Plaintiffs respond that it would be unfair to require Dr. Margolis to opine about defects in Defendants’ mesh because the MDL court “repeatedly held that experts may not provide opinion testimony that . . . uses a legal term of art . . . [such as] ‘defective.’” Opp’n Mem. at 9 (citing In re: Ethicon, 2016 WL 4536885, at *4) (other citations omitted). Of course, this Court defers to previous rulings of the MDL court, see Deutsch, 768 F. Supp. 2d at 428 (“Orders issued by a federal transferee court [in an MDL] remain binding if the case is sent back to the transferor court.”), but the Court sees no obstacle to Dr. Margolis attributing Mrs. Balura’s injuries to “features” or “characteristics” of Defendants’ mesh instead of particular “defects.” In this way, Dr. Margolis could describe what attribute of Defendants’ mesh caused Mrs. Balura’s injuries without straying toward the proscribed language. Thus, with respect to Plaintiffs’ design defect claim, Dr. Margolis’ opinion is inadmissible.

ii. Other Causes of Action

Not so, however, with Plaintiffs’ other claims, such as failure to warn, loss of consortium, and punitive damages.

In a failure-to-warn claim, the “defect” is the failure to warn itself. See Wickenden v. Saint-Gobain Performance Plastics Corp., No. 17-CV-1056, 2018 WL 3069193, at *6 (N.D.N.Y. June 21, 2018) (Kahn, J.) (“To state a prima facie case of liability on the basis of a defendant’s failure to warn, the plaintiff must establish that . . . the manufacturer had a duty to warn [and] the

manufacturer breached the duty to warn in a manner that rendered the product defective, i.e., reasonably certain to be dangerous” (internal quotation marks omitted). Thus, Dr. Margolis’ lack of specificity about the “defect” that caused Mrs. Balura’s injuries is immaterial. See Margolis Report at 3–4. And Dr. Margolis’ testimony will help the jury understand the nature and extent of Mrs. Balura’s injuries, a necessary element of her failure-to-warn claim. See Wickenden, 2018 WL 3069193, at *6 (“[A] failure to warn . . . plaintiff must establish [that she] suffered loss or damage”). Further, Dr. Margolis’ testimony about Mrs. Balura’s injuries might bear on Plaintiffs’ claim for punitive damages, see Romaine v. Rawson, 140 F. Supp. 2d 204, 214 (N.D.N.Y. 2001) (looking to “severity of [p]laintiff’s injuries” in determining punitive damages award), and their claim for loss of consortium, see Hogan v. Cty. of Lewis, N.Y., No. 11-CV-0754, 2015 WL 1400496, at *16 (N.D.N.Y. Mar. 26, 2015) (noting that loss of consortium depends on “demonstrat[ing] a physical injury”), aff’d sub nom. Okudinani v. Rose, 779 F. App’x 768 (2d Cir. 2019). Dr. Margolis’ opinion attributing Mrs. Balura’s injuries to Defendants’ mesh will thus be helpful to the jury as to these non-design-defect claims.

As described above, the Court has already determined that Dr. Margolis’ opinion is sufficiently reliable to be admissible. Therefore, so long as Dr. Margolis is qualified to offer his opinions, Daubert will be satisfied and the Court can admit Dr. Margolis’ testimony as to Plaintiffs’ non-design-defect claims. Defendants have not challenged Dr. Margolis’ qualifications, see Reply at 3 (“Ethicon d[oes] not challenge Dr. Margolis’ qualifications”), and even if they had, the Court would find that Dr. Margolis is qualified. “Dr. Margolis is a pelvic surgeon and a urogynecologist with experience implanting and removing sling systems.” In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig., No. 12-CV-4301, 2014 WL 186872, at *15 (S.D.W. Va. Jan. 15, 2014). He is board certified in obstetrics and gynecology and in female

pelvic medicine and reconstructive surgery. Opp'n Exs. at 62. "He has explanted over 200 mesh slings, including the TVT device[,] [and] has additionally observed numerous sling and mesh procedures involving TVT products . . ." In re Ethicon, 2014 WL 186872, at *17. The MDL court previously ruled that Dr. Margolis was qualified to offer an opinion on general causation. Id. at *15–17. The Court similarly finds that Dr. Margolis is qualified to offer a specific causation opinion and, therefore, denies the Motion to Exclude as to Plaintiffs' non-design-defect claims.

c. Dr. Margolis' Opinions About Mrs. Balura's Risk of Future Complications

Defendants argue finally that Dr. Margolis' opinion that Mrs. Balura is at risk of ongoing complications such as "future delayed erosions," "dyspareunia," and "worsening urinary incontinence" is unreliable. Mot. to Exclude Mem. at 8–9. Specifically, Defendants argue:

Dr. Margolis . . . speculates that Ms. Balura is "at risk for future delayed erosions" and "it is more likely than not that she will suffer this complication in the future." . . . While he references Ms. Balura's history as evidence for his conjecture, Ms. Balura has not had an erosion since it was resolved by the excision procedure in 2013. Dr. Margolis also suggests that Ms. Balura will continue to have dyspareunia, have "worsening" urinary incontinence that will require future surgeries, which will be "far more complicated" and "more likely than not will increase scarring, related pain and tissue damage." . . . He fails to substantiate these generalized complication probabilities with any support in either the medical record or scientific literature. . . . Such speculation is therefore inadmissible.

Id. at 9.

For their part, Plaintiffs argue that "Mrs. Balura testified that she still has to use pads to treat her incontinence and she still suffers from dyspareunia[,] [t]herefore, [it] is not speculation to opine that these complications will continue in the future as they have continued from the time of her revision surgery to the present day." Opp'n at 9. And they assert:

Dr. Margolis' opinion that Mrs. Balura is at risk of future erosions is not conjecture. There is no question that Mrs. Balura has already suffered an

erosion of the mesh from the TVT device. Nor is there a question that mesh remains inside Mrs. Balura's body. At deposition on June 22, 2017, Dr. Robert Lobel's testimony described only a 'two centimeter' piece of eroded mesh having been removed. . . . Dr. Margolis opines that 'given [Mrs. Balura's] history' (one mesh erosion already) it is more likely than not that she will suffer this complication in the future. This opinion, based on testimony and records, is well within the expertise of Dr. Margolis and, therefore, admissible.

Id. at 9–10.

The Court is inclined to agree with Defendants. Dr. Margolis fails to explain why he believes that it is more likely than not that Mrs. Balura is "at risk for future delayed erosions" when Ms. Balura has apparently not had an erosion since 2013. "[W]hen an expert opinion is based on [purported] data . . . that are simply inadequate to support the conclusions reached," that opinion should be excluded. Deutsch, 768 F. Supp. 2d at 426; see also In re Zyprexa Prods. Liab. Litig., No. 04-MD-1596, 2009 WL 1357236, at *2 (E.D.N.Y. May 12, 2009) ("Subjective or intuitive guesswork, as well as testimony that is insufficiently connected to the facts of the case, are grounds for rejection of a proffered expert's testimony."). And while it seems perfectly plausible to the Court that Mrs. Balura will continue to suffer from dyspareunia and incontinence and, and that her incontinence could even worsen as Dr. Margolis predicts, without more information about Dr. Margolis' reasons for and methods in arriving at this conclusion, the Court cannot admit it under Daubert. See Daubert, 509 U.S. at 595 ("[T]he district court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court's belief as to the correctness of those conclusions."); Amorgianos, 303 F.3d at 267 (exhorting district courts to examine "the method by which the expert draws an opinion from th[e] facts, and how the expert applies the facts and methods to the case at hand").

Therefore, the Court grants Defendants' motion to exclude Dr. Margolis' opinion as to Mrs. Balura's future complications.

IV. CONCLUSION

Accordingly, it is hereby:

ORDERED, that Plaintiffs' request for dismissal (Dkt. No. 39) is **GRANTED** and the following causes of action are **DISMISSED** from this case: Count I – Negligence – Manufacturing Defect; Count II – Strict Liability – Manufacturing Defect; Count IV – Strict Liability – Defective Product; Count VI – Common Law Fraud; Count VII – Fraudulent Concealment; Count VIII – Constructive Fraud; Count IX – Negligent misrepresentation; Count X – Negligent Infliction of Emotional Distress; Count XI – Breach of Express Warranty; Count XII – Breach of Implied Warranty; Count XIII – Violation of Consumer Protection Laws; Count XV – Unjust Enrichment; and Count XVIII – Discovery Rule and Tolling; and it is further

ORDERED, that the following claims may proceed: Count I – Negligence – Failure to Warn and Design Defect; Count III – Strict Liability – Failure to Warn; Count V – Strict Liability – Design Defect; Count XIV – Gross Negligence; Count XVI – Loss of Consortium; Count XVII – Punitive Damages; and it is further

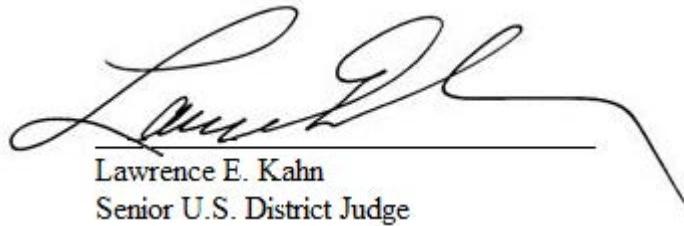
ORDERED, that Defendants' motion for partial summary judgment (Dkt. No. 34) is **DENIED** as moot; and it is further

ORDERED, that Defendants' motion to exclude the expert opinion and testimony of Dr. Michael T. Margolis (Dkt. No. 37) is **GRANTED** as to Dr. Margolis' opinions on plaintiff Cathy Balura's likelihood of future complications, and, with respect only to Plaintiffs' design defect claims, that "Ms. Balura's pelvic injuries were caused by the defective TVT device." The motion is otherwise **DENIED**; and it is further

ORDERED, that the Clerk serve a copy of this Decision and Order on all parties in accordance with the Local Rules.

IT IS SO ORDERED.

DATED: February 19, 2020
Albany, New York



Lawrence E. Kahn
Senior U.S. District Judge